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**NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC
OF CHINA**

中华人民共和国国家标准

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**Evaluating Method and Standard for the Efficacy of
Disinfection and Sterilization**

消毒与灭菌效果的评价方法与标准

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National Standard of the People's Republic of China

Evaluating Method and Standard for the Efficacy of Disinfection and Sterilization

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Chapter I Evaluating Method and Standard for the Efficiency of Pressure Steam Disinfection

1 Subject and Scope

The method specifies the technical standard for pressure steam disinfection and the test method to evaluate the efficiency of such disinfection.

The method is applicable to evaluate the efficiency of pressure steam disinfection.

2 Reagent

Unless otherwise specified, all reagent used by the standard shall be analytical reagent (AR) and the water used shall be distilled.

2.1 Peptone

2.2 Glucose

2.3 Bromocresol purple alcohol solution: dissolve 2.0g bromocresol purple into 100mL 95% ethyl alcohol.

2.4 Preparation of bromocresol purple peptone water medium: dissolve 10.0g peptone and 5.0g glucose into 100mL distilled water; adjust its PH to 7.0-7.2; add 0.6mL 2% bromocresol purple alcohol solution in the solution and shake it; distribute 5mL solution in each test tube and seal these test tubes; place these test tubes in a pressure steam sterilizer for disinfection at 115°C; Then store these test tubes for future use.

3 Indicative Bacteria

Bacillus stearothermophilus spore (ATCC7953 or SSIK31) Tablet. Each tablet contains 5×10^5 - 5×10^6 bacteria. At 121°C, the time D_{121} for sterilizing 90% microorganism is 1.3-1.9 min with killing time (KT) ≤ 19 min and survival time (ST) ≥ 3.9 min.

4 Chemical Indicator

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Any chemical indicator approved by Ministry of Health.

5 Technical Requirements

Pressure Steam Sterilizer	Pressure, MPa/cm ²	Temperature, °C	Sterilizing Time
Downward Exhaust Type	0.070	115	40
	0.105	121	30
Fore-Vacuum Type	0.210	134	4~6

6 Test Method

6.1 Biological Indicator (the basis for evaluating the efficiency of pressure steam sterilizing equipment)

6.1.1 Put two tablets of *Bacillus stearothermophilus* spore into a sterilizing paper bag and place the bag in the center of a standard test pack.

6.1.2 Place a standard test pack respectively at the center of the upper and middle layers and the exhaust port in the sterilization cabinet (the test pack shall be 25cm x 30cm x 30cm, wrapped by 3 tabby long-sleeved surgical gowns, 4 small-sized operating towels, 2 middle-sized operating towels, 1 large-sized operating towel, and 30 10cmx10cm 8-layer gauze dressings). As for a portable pressure steam sterilizer, use a ventilated storage box (22cmx13cmx6cm) to replace above standard test pack. Middle-sized test tubes shall be fully placed in such box and tablets of indicative bacteria shall be put into two sterilizing tubes at the center, the opening of which shall be sealed by kraft paper. Then the box shall be placed evenly at the bottom of the sterilizer.

6.1.3 After a sterilization cycle, the tablets in above standard test pack or ventilated storage box shall be taken out under aseptic condition. Then the tablets shall be put into bromocresol purple peptone water medium to be cultured for 48h at 56°C. Observe the change of the medium's color.

6.2 Chemical Indicators

Use a chemical indicator tape outside the pack to indicate whether its article has gone through sterilizing process. Use a chemical indicator at the center inside the pack as a reference to indicate whether its article is sterilized.

7 Result Determination & Assessment



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